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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,295	04/25/2001	Noel Caplice	07039-175001	7824

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/843495

Applicant(s)

Caplice et al

Examiner

A/GH

Group Art Unit

1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 1/22/03
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-37 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-37 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

The amendment of 1/22/03 canceled claims 38 and 39 and amended claim 7.

Claims examined on the merits are 1-37 which are all claims in the application.

5 ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

10 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15 Claims 1-4, 12, 13, 24-26 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Ducheyne (5,030,233).

The claims are drawn to an implantable medical device comprising a non-woven framework of metal fibers and pores having an average size of at least 40 μ m.

20 Ducheyne disclose a porous metal material for surgical implantation made of metal fibers such as stainless steel or titanium (col 12, lines 45-46), and having a pore size of at least 150 micrometers (col 12, lines 49-50. The material is made by sintering the fibers together (col 7, lines 25-45). As shown by Figure 1, the material is non-woven.

25 The implant made from metal fibers disclosed by Ducheyne is the same as presently claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

5 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 20 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-7, 14-20 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ducheyne in view of Vacanti et al (5,567,612).

The claims require the device to contain extracellular matrix protein, cells and/or the fibers to made from a polymer.

25 Vacanti et al disclose an implant for generating tissue which can be made of polymer fibers (col 5, lines 45-52), can be coated with extracellular matrix protein (col 5, lines 15-20) and can contain cells (col 6, lines 5-10).

It would have been obvious to provide the metal fiber implant of 30 Ducheyne with extracellular matrix protein and/or cells for their

expected function as disclosed by Vacanti et al. It would have been further obvious to use polymer fibers in place of metal fibers since it would have been apparent from Vacanti et al that polymer fibers can provide the same type of function as the metal fibers when constructing
5 an implant.

Claims 8, 21-23 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 5-7, 14-20 and 32-34 above, and further in view of Ferrara et al (6,455,283 B1).

The claims require cells that express a polypeptide such as
10 vascular endothelial growth factor.

Ferrara et al disclose transforming cells to produce vascular endothelial cell growth factor with a nucleic acid encoding the factor.

When providing cells in the metal fiber implant of Ducheyne as set forth above, it would have been obvious to use cells encoded to produce
15 vascular endothelial growth factor as disclosed by Ferrara et al to obtain the expected function of the growth factor to promote the growth of cells contained by the implant.

Claims 9-11 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 5-7, 14-20 and 32-
20 34 above, and further in view of Davidson (5,690,670).

The claims require the implant to be in the form of a stent or vascular graft.

Davidson discloses stents or vascular grafts made fabricated from a metal alloy (abstract and col 4, lines 6-40).

It would have been obvious to make the metal fiber implant of Ducheyne in the form of a stent and vascular graft to obtain their expected function as disclosed by Davidson when made of a metal alloy.

Any inquiry concerning this communication or earlier communications
5 from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

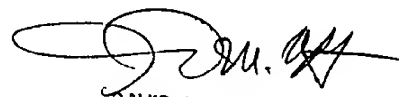
If attempts to reach the examiner by telephone are unsuccessful, a
10 message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or
15 (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651